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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,130	02/12/2001	Vic C. Knauf	16518.052	2541

28381 7590 02/13/2004

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EXAMINER
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FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/782,130	KNAUF ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants are notified that this application has been scanned into the Image File Wrapper System. During that scanning process, pages 6 and 16 of the original specification were misplaced. Applicants are requested to submit copies of these original pages with their response to this Office action, together with a declaration that said pages are the original specification pages and do not contain new matter. The mistake is regretted. Applicants' assistance is appreciated.

Claims 17-54 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,420,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented on page 2 of the last Office action.

Claims 17-54 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,608,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented on page 2 of the last Office action.

Claims 17-54 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,981,839. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because of the reasons presented on pages 2-3 of the last Office action.

Claims 17-54 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,281,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented on page 3 of the last Office action.

Claims 17-54 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-29, 81-130, 133 and 136-138 of copending Application No. 09/574,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented on pages 3-4 of the last Office action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants' intent to file Terminal Disclaimers is noted. The rejections will be maintained until receipt of properly executed Terminal Disclaimers.

Claims 17-54 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to seed-specific promoters from Brassica including the napin, acyl, carrier protein, and EA9 promoters, does not reasonably provide enablement for claims broadly drawn to any seed-specific promoter from any plant genus or species, or for the cruciferin promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 4-7 of the last Office action.

Claims 17-54 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 7-9 of the last Office action.

Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zambryski et al taken with Sengupta-Gopalan et al, as stated on pages 10-11 of the last Office action.

Claims 20, 33, 38 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zambryski et al taken with Sengupta-Gopalan et al as applied to claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 above, and further in view of Pedersen et al, as stated on pages 11-12 of the last Office action.

Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al (U.S. 5,504,200) taken with Sengupta-Gopalan et al, as stated on pages 12-14 of the last Office action.

Claims 20, 33, 38 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al taken with Sengupta-Gopalan et al as applied to claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 above, and further in view of Zambryski et al taken with Pedersen et al, as stated on pages 14-16 of the last Office action.

Claims 48-49 remain free of the prior art, as stated on page 16 of the last Office action.

No claim is allowed.

Applicants' arguments filed 10 November 2003 have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection is improper, given the disclosure in the specification and the prior art of various seed-specific promoters from various plant species, and the disclosure in the specification of how to isolate other seed-specific promoters. Applicants also cite *Engel Industries, Inc. v. Lockformer Co.* and *The Johns Hopkins University v. CellPro, Inc.* to support their position.

The Examiner maintains that the excerpted portions of the specification are insufficient to enable the broadly claimed invention. Pages 35-55 demonstrate the isolation of seed-specific promoters from Brassica only. A cDNA clone encoding acyl carrier protein from spinach did not include the promoter region. Furthermore, isolation of the cruciferin gene or its associated promoter was not demonstrated. Page 15 merely provides a wish list of other genes and plants from which to isolate promoters, and pages 62-63 only provide brief suggestions of method steps which could be utilized. As taught by *Bayer v. Housey*, Fed. Cir. 2003, Appeal No. 02-1598, "processes of identification and generation of data are not steps in the manufacture of a final ... product".

Regarding the state of the prior art, please see *Genentech* cited previously.

Regarding *Engel*, the Examiner notes that the Decision focused on best mode requirements, and only briefly mentioned enablement by distinguishing it from best mode. The Court in *Engel* also noted that the district court did not demonstrate a lack of enablement, so that a similar finding could not be reached or upheld by the Federal Court. See 20 USPQ2d 1300 at 1304. Thus, *Engel* cannot be relied upon for any substantive teaching about the requirements for enablement, and certainly does not refute the requirements set forth in *In re Wands*, which requirements were relied upon by the Examiner in the first Office action.

Regarding *Johns Hopkins*, different fact patterns were involved. In that case, Patentee claimed antibodies *per se*, and the infringer unsuccessfully argued that claims to the antibodies were not enabled since not all of the disclosed methods for making them would work. The Federal Court found that since the specification taught at least one operable way to make the antibodies, claims to the antibodies themselves were enabled. The breadth of the patent claims regarding the type of antibody was not at issue. In the instant application, it is the breadth claims directed to the products, i.e. the seed-specific promoters, and methods of using them, that is at issue. Applicants do not propose multiple methods to obtain a single seed-specific promoter. Instead, Applicants provide only one method for obtaining seed-specific promoters from one plant genus, while claiming any seed-specific promoter from any plant genus, and methods of their use. Furthermore, the Court in *Hopkins* upheld the enablement of the patent claims because the infringer improperly relied upon the experiences of unskilled

artisans, rather than ordinarily skilled artisans, to demonstrate unpredictability (see 47 USPQ2d 1705 at page 1718).

Applicants urge that the written description rejection is improper, given the disclosure in the specification and the prior art of various seed-specific promoters from various plant species, the disclosure in the specification of how to isolate other seed-specific promoters, and the lack of a requirement that “every nuance of the claims is explicitly described in the specification” if “a person of ordinary skill in the art” would have otherwise “understood the inventor to have been in possession of the claimed invention at the time of filing”, as taught by *In re Alton* (Response, page 4, top paragraph).

The Examiner maintains that neither the specification nor the prior art provide any guidance regarding the identification of any structural features, i.e. conserved DNA sequences, common to all seed-specific promoters, as required by MPEP 2163, *Lilly*, and the Written Description Guidelines, all cited previously. Thus, inadequate written description of the broadly claimed genus, which encompasses all seed-specific promoters from all unrelated plant genera and species, has been provided by Applicants’ disclosure of the isolation of three seed-specific promoters from *Brassica* genes. See also *Bayer v. Housey* cited above.

Regarding *Alton*, the Examiner maintains that different fact patterns were involved, and that *Alton* is not conclusive. In that case, Applicant narrowly claimed a particular gamma interferon analog with deletions of particular amino acid residues. The Court found that the Examiner failed to adequately address Appellants’ submission



of a declaration demonstrating that Appellants were in possession of the particularly claimed analog. The Court then remanded the case to the Patent Board of Appeals and Interferences for further evaluation of the declaration (see 37 USPQ2d 1578 at 1582 and 1584). Such a remand demonstrates that the Court did not yet recognize Appellants to have been in possession of the claimed invention, and did not believe that a person of ordinary skill would have understood this to be the case.

In the instant case, Applicants are broadly claiming any and all seed-specific promoters from any and all plant genera and species. Applicants have not provided any declaration or other evidence that they were in fact in possession of seed-specific promoters from any plant genus other than *Brassica* at the time of filing.

Applicants urge that the art rejections involving Sengupta-Gopalan et al are improper, given the support in the earliest-filed parent application for seed-specific promoters, which application predates Sengupta-Gopalan et al, and given the knowledge in the art of such promoters as taught by Murai et al. The Examiner maintains that the mere recitation in the parent application of a *light-inducible* promoter does not provide any enablement for isolated *seed-specific* promoters or methods of their use for plant transformation. The parent application does not demonstrate the identification or isolation of any seed-specific gene or its promoter, or plant transformation therewith. Applicants may not rely solely upon Murai et al to enable the earliest parent application regarding seed-specific promoters and methods for their use. See *Genentech* cited previously. Thus, the claimed subject matter was not adequately disclosed under 35 USC 112, first paragraph, in the parent application, so that

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Applicants are not entitled to the benefit of the earlier filing date, per *Tronzo* cited by Applicants.

Applicants urge that the art rejection over *Zambryski et al* taken with *Sengupta-Gopalan et al* is improper, given the failure of either reference taken by itself to teach or suggest the use of a seed-specific promoter ligated to “a DNA sequence of interest other than the native coding sequence” of the gene from which the seed-specific promoter was isolated, as recited in instant claim 17. The Examiner maintains that the references *taken together* provide the suggestion to combine their teachings and obtain plant transformation with a DNA construct comprising the seed-specific phaseolin promoter of *Sengupta-Gopalan et al* ligated to a heterologous coding sequence such as the antibiotic resistance marker gene of *Zambryski et al*, as stated in the last Office action. Furthermore, Applicants’ arguments on the bottom of page 4 of the Response, that *Murai et al* demonstrated the use of seed-specific promoters in plant transformation constructs, contradict Applicants’ assertions that *Sengupta-Gopalan et al* failed to provide such a teaching, since both references teach the phaseolin promoter ligated to the phaseolin coding sequence and plant cells transformed therewith.

Applicants urge that the art rejection over *Zambryski et al* and *Sengupta-Gopalan et al*, further in view of *Pedersen et al*, is improper because *Pedersen et al* does not address the deficiencies of the other references. The Examiner maintains that the other references taken together are not deficient, as discussed above.

Applicants urge that the art rejection over *Hall et al* taken with *Sengupta-Gopalan et al* is improper, given the failure of either reference taken by itself to teach or suggest

the use of a seed-specific promoter ligated to a DNA sequence of interest which is other than the native coding sequence of the gene from which the seed-specific promoter was isolated. The Examiner maintains that the references *taken together* provide the suggestion to combine their teachings and obtain plant transformation with a DNA construct comprising the seed-specific phaseolin promoter of Hall et al or Sengupta-Gopalan et al ligated to a heterologous coding sequence such as the antibiotic resistance marker gene also taught by Hall et al, as stated in the last Office action. It is also noted that Hall et al teach a DNA construct comprising the phaseolin promoter ligated to an intronless cDNA phaseolin coding sequence, as stated in the last Office action, which cDNA constitutes a DNA sequence "other than the native coding sequence of [the phaseolin] gene", as the native coding sequence would contain introns.

Applicants urge that the art rejection over Hall et al taken with Sengupta-Gopalan et al, further in view of Zambryski et al and Pedersen et al, is improper, since the tertiary and quaternary references do not cure the deficiencies of the primary and secondary references. The Examiner maintains that the primary and secondary references taken together are not deficient, as stated above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 2, 2004

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180

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